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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In Re Bard IVC Filters Products
Liability Litigation

No. MD-15-02641-PHX-DGC

(Oral Argument Requested)

PLAINTIFF'S MOTION *IN LIMINE*
NO. 4: BARD'S INTERNAL RATES
BASED ON REPORTING RATES OF
FILTER COMPLICATIONS

(Assigned to the Honorable David G.
Campbell)

(Tinlin Bellwether Case)

Plaintiffs respectfully move *in limine* for an Order precluding evidence, testimony, or argument that Bard conducted a decade's worth of internal investigation revealing Recovery filters were "99.9 percent effective" and the failure rates were only between .24%-.84% for perforation, migration, tilt, and fracture, as captured in Bard's chart of reported events, discussed below. This evidence is not only irrelevant and inadmissible as hearsay, but what little, if any, probative value is greatly outweighed by the danger of misleading the jury, unfair prejudice, and confusion of issues and should be precluded pursuant to Federal Rules of Evidence 403, 802 and 803(6)(E).

MEMORANDUM OF POINTS AND AUTHORITIES

I. Bard's Alleged Internal Rates Are Hearsay Which Lack Trustworthiness

Under Rules 802 and 803(6)(E), hearsay will be excluded if there is a lack of

1 trustworthiness in “the source of information or the method or circumstances of
2 preparation.” Based on the previous trial records, Plaintiffs anticipate Defendants will
3 attempt to use or reference a self-serving chart they created from their own internal
4 database, without any way to substantiate the data they claim supports their rates of failure
5 or effectiveness. *See* Exhibit A, Trial Ex. 5874 (not admitted) Bard IVC Filter Chart BPV-
6 17-01-00261741; *see also* Exhibit B, *Hyde v. Bard* Trial Tr. 120:20-123:11 and 1785:7-9;
7 Exhibit C, *Booker v. Bard* Trial Tr. at 2352: 8-13, 25-2353:6, 2374:2-2375:7, 2376:19-22.
8 Bard has admitted, however, that these rates do not reflect “what the rate is in the real world”
9 or the “actual rate,” and do not account for underreported adverse events or asymptomatic
10 failures as of December 2016. *Id.* In fact, Bard was previously precluded by this Court in
11 *Hyde* from using the rates to argue to the jury its filters were “99.9 percent effective,” with
12 defense stating, “I have no data that I could present to the jury that would show that....” *See*
13 Exhibit B, at 120:20-123:11.

14 Moreover, the FDA determined Bard was under-reporting adverse events associated
15 with their filters by misclassifying them. On July 13, 2015, the FDA served Defendants
16 with a formal warning for inadequately evaluating and misclassifying adverse events
17 associated with its IVC filter product lines, among other things. *See* Exhibit D, *Hyde* Trial
18 Ex. 1680, FDA Warning Letter, July 13, 2015.

19 Also, according to Defendants’ own staff vice president of corporate clinical and
20 medical affairs, only one to five percent of all adverse events are ever even reported to
21 Bard. Exhibit E, Ciavarella Dep. November 12, 2013, at 128:10 to 128:18. Likewise, Dr.
22 Darren Hurst testified that approximately one to two percent of adverse events are
23 reported. Exhibit C, at 845:5 to 845:7. This is apparent in light of the astonishingly low
24 number of failures listed in Bard’s chart, as compared to the over 4,000 cases currently
25 pending in this MDL, with individual plaintiffs injured by Bard filter failures (fractures,
26 migrations, perforations, tilt, etc.), not to mention the plaintiffs’ cases filed in state courts.

27 Additionally, there is no way to substantiate the rates in the chart, and no way to
28 know which complaints and failures were included or excluded, as Plaintiffs have never

1 been provided with the data used to prepare the chart. Further, these rates are based on
 2 Bard's filter sales, *not* patients with IVC implants, or more appropriately, scanned or
 3 monitored patients with IVC implants.

4 Finally, Bard had a clear incentive to skew this data. Thus, Bard's so-called
 5 internal rates are not an accurate or appropriate indicator, and the data cannot be trusted.
 6 In light of the above, the chart not only qualifies as inadmissible hearsay under Rule 802,
 7 it fails the requirements of 803(6), and especially fails the trustworthiness requirement.¹

8 **II. Bard's Alleged Internal Rates Are More Prejudicial than Probative**

9 Pursuant to Rule 403, relevant evidence may be excluded if its probative value is
 10 substantially outweighed by the danger of unfair prejudice, confusion of the issues,
 11 misleading the jury, wasting time, or needlessly presenting cumulative evidence. The court
 12 should determine whether evidence properly admissible should, nevertheless, be excluded
 13 as unduly prejudicial; that determination is to be made by balancing the probative value of
 14 the evidence against the prejudicial effect the evidence would have on those hearing it.

15 In addition to the above issues of trustworthiness, the overwhelming evidence in this
 16 case shows Bard was well aware: the Recovery was failing at rates "significantly higher"
 17 than the available alternative filters, including its own SNF (which was not included in the
 18 chart); was fracturing at rates **28.33 times higher** than the overall rate for all IVC filters on
 19 the market; "[r]eports of death, filter migration (movement), IVC perforation, and filter
 20 fracture . . . were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rates for all
 21 filters[,] . . . differences [that] were all **statistically significant**;" the Recovery filter was
 22 deemed **not reasonably safe for human use**; and Bard's own head of Clinical Affairs
 23 determined Bard should have warned doctors of the higher reported failure rates associated
 24 with the Recovery. *See* Exhibit F, Trial Ex. 2052, HHE December 17, 2004, p. 1 ¶1; Exhibit
 25 G, HHE July 9, 2004; Exhibit. H, Uelmen Dep. October 4, 2013, at 326:2 to 326:19; Exhibit
 26 E, Ciavarella Dep. November 12, 2013, at 250:2 to 250:7.

27 ¹ Should such self-serving statements be permitted, Plaintiffs should be permitted to
 28 summarize all legal complaints filed and pending against Defendants throughout the
 country, along with the internal complaint files and MAUDE data to counter this evidence.

Defendants' references to the internal failure rates from the chart or "99.9 percent effective" rates are Bard's attempts to misinform and confuse. Thus, Bard must be precluded from attempting to mislead or confuse the jury with their false claims and references to internal studies and analysis showing low failure rates, including the above referenced chart. Such evidence would unduly prejudice Plaintiffs in this case and should be precluded pursuant to Rule 403.

III. Conclusion

Based upon the foregoing, Plaintiffs respectfully request Defendants be precluded from introducing evidence, testimony, or argument that Bard conducted a decade's worth of internal investigation revealing Recovery filters were "99.9 percent effective" and the failure rates were only between .24%-.84% for perforation, migration, tilt, and fracture, as captured in Bard's chart of reported events, and for such other and further relief to which Plaintiffs may be entitled.

RESPECTFULLY SUBMITTED this 29th day of March, 2019.

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By: /s/ Mark S. O'Connor

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CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of March, 2019, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine